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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/657,017	09/05/2003	Juan DePablo	096429-9144	9034
23510	7590	10/06/2004	EXAMINER	
MICHAEL BEST & FRIEDRICH, LLP ONE SOUTH PINCKNEY STREET P O BOX 1806 MADISON, WI 53701			SNEDDEN, SHERIDAN	
			ART UNIT	PAPER NUMBER
			1653	

DATE MAILED: 10/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/657,017	Applicant(s) DEPABLO ET AL.	
	Examiner Sheridan K Snedden	Art Unit 1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 14-28 is/are pending in the application.
 4a) Of the above claim(s) none is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 14-28 is/are rejected.
- 7) ☒ Claim(s) 14-28 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>1/26/2004</u> . | 6) <input type="checkbox"/> Other: ____. |

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DETAILED ACTION

1. Applicant's cancellation of claims 1-13 and 29-45 filed 9/5/2003 is acknowledged.

Claims 14-28 are pending.

Claim Objections

2. Claim 23 objected to because of the following informalities:

At claims 23, line 4, a space should be inserted between the words "of" and "polyhydroxy." Appropriate correction is required.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 23 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 23 recites the limitation "polyhydroxy compound" at line 4. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claim 14, 16, 17 and 19-21 are rejected under 35 U.S.C. 102(b) as being anticipated by Ahmad *et al.* (Transplant Proc. 1997 Feb-Mar;29(1-2):355-6; IDS). Ahmad *et al.* teach a phosphate buffered sucrose (PBS140) solution, pH 7.0, used for kidney preservation (claims 14, 16, 17). Cold storage was used to preserve the medium (page 355, column 2). PBS140 comprises 69mM of sodium phosphate and 140mM sucrose, which represents a ratio of phosphate ions to hydroxyl group of 0.062 or about 0.0625 (see table 1; claim 21). The amount of sucrose in the solution is 5% or about 10% (claim 19, 20). The recitation of 'a biological material' is interpreted as any biological material and not necessarily present in a significant amount as to alter the molar ratios and percent compositions of the other components in the preservation material. Thus, the method of making and preserving a preservation medium is taught and the reference clearly anticipates the invention as recited in the claims.

6. Claims 14-28 are rejected under 35 U.S.C. 102(b) as being anticipated by Roser (US Patent 4,891,319; IDS). Roser, and reference therein, teaches that trehalose is superior to other carbohydrates in protecting biological material during freezing and dehydration processes (see column 1, lines 45-47). Roser teaches a specific aqueous solution to protect proteins from denaturing during the drying process in which the desirable concentration of trehalose is from 0.05-20% (column 2, line 45) and states that the amount of trehalose required depends on the content of protein (column 3, lines 21-25). Roser taught that the preservation medium is used in a method of protecting proteins and macromolecules against denaturation during the drying process, of which ambient-air drying is preferred (column 2). Examples 1-4 of Roser teaches the

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use of a phosphate buffer. Example 3 specifically teaches the use of phosphate buffered saline, or PBS (150mM phosphate, pH 7.2; see Sigma product number P0261) and a final concentration of trehalose of 5% or about 10%. The 5% trehalose solution of Example 3 is estimated to be about 150mM trehalose and would have a ratio of phosphate ions to hydroxyl group of about 0.125 and a ratio of phosphate ions to trehalose of about 1. Example 3 also teaches that the mixture may be dehydrated. In addition, Example 10 teaches that the amount used depends on the protein concentration of the sample and teaches concentrations of trehalose up to 500mM. Thus, the method of making and preserving a preservation medium is taught and the reference clearly anticipates the invention as recited in the claims.

7. Claims 14-28 are rejected under 35 U.S.C. 102(b) as being anticipated by Carpenter et al. (Patent # 4,806,343; IDS). Carpenter et al. discloses a composition made for use in a method of protecting biological material, i.e. proteins, in order to preserve their biological activity.

Examples 1, 5 and 9 of Carpenter et al. disclose aqueous solutions having 25-300 mM polyhydroxy carbohydrate, specifically trehalose and 10mM and 100mM sodium phosphate, pH 8. The Carpenter *et al.* solution which contains at 300mM trehalose, (9.9% which reads upon the recitation of about 10%) and 100mM Phosphate, corresponds to a molar ratio of phosphate ions to hydroxyl groups of 0.04, and to a molar ratio of phosphate ions to trehalose of 0.3. The above preservation medium is used in a method of freezing drying red blood cells. Thus, the method of making and preserving a preservation medium is taught and the reference clearly anticipates the invention as recited in the claims.

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Conclusion

8. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheridan K Snedden whose telephone number is (571) 272-0959.

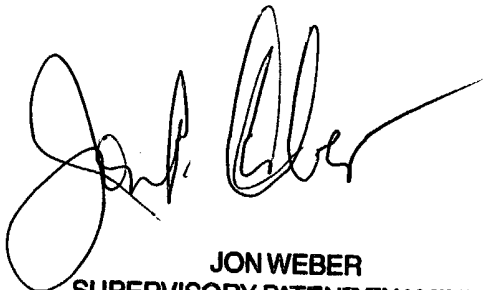
The examiner can normally be reached on Monday - Friday, 8:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on (571) 272-0925. The fax phone number for regular communications to the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

SKS
October 1, 2004

SKS



JON WEBER
SUPERVISORY PATENT EXAMINER